

# EXHIBIT N

Elaine Duncan

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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON

IN RE: ETHICON, INC. : Master File No.  
PELVIC REPAIR SYSTEM : 2:12-MD-02327  
PRODUCTS LIABILITY LITIGATION : MDL 2327  
:  
: JOSEPH R.  
THIS DOCUMENT RELATES TO : GOODWIN  
THE FOLLOWING CASES IN : US DISTRICT  
WAVE 1 OF MDL 200: : JUDGE

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Myra Byrd, et al. v. Ethicon, Inc., et al.  
Civil Action No. 2:12-cv-00748  
Angela Coleman, et al. v. Ethicon, Inc., et al.  
Civil Action No. 2:12-cv-01267

Dina Destefano-Raston, et al. v. Ethicon, Inc., et al.  
Civil Action No. 2:12-cv-01299  
Rose Gomez, et al. v. Ethicon, Inc., et al.  
Civil Action No. 2:12-cv-00344

Dawna Hankins v. Ethicon, Inc., et al.  
Civil Action No. 2:12-cv-00369  
Donna Hankins, et al. v. Ethicon, Inc., et al.  
Civil Action No. 2:12-cv-01011

Wilma Johnson v. Ethicon, Inc., et al.  
Civil Action No. 2:11-cv-00809  
Debra Lynn Joplin v. Ethicon, Inc., et al.  
Civil Action No. 2:12-cv-00787

Margaret Kirkpatrick v. Ethicon, Inc., et al.  
Civil Action No. 2:12-cv-00746  
Paula Kriz, et al. v. Ethicon, Inc., et al.  
Civil Action No. 2:12-cv-00938

Miranda Patterson v. Ethicon, Inc., et al.  
Civil Action No. 2:12-cv-00481

DEPOSITION OF ELAINE DUNCAN  
MARCH 31, 2016

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1                   Deposition of Elaine Duncan, taken  
2   pursuant to notice, was held at the law offices of Nilan  
3   Johnson Lewis, PA, 120 South Sixth Street, Suite 400,  
4   Minneapolis, Minnesota 55402, commencing at 10:20 a.m. on  
5   the above date, before Barbara J. Carey, Registered  
6   Professional Reporter and Notary Public in and for the  
7   State of Minnesota.

8   WHEREUPON, the following proceedings were duly had:

9   (The oath was administered by the reporter.)

10                   WITNESS RESPONSE: I do.

11                   THE REPORTER: Thank you.

12                   ELAINE DUNCAN,

13   after having been first duly sworn, was called as a  
14   witness and testified as follows:

15                   EXAMINATION

16   BY MR. WALLACE:

17                   Q.   Good morning, Ms. Duncan. We met before;  
18   right?

19                   A.   Yes.

20                   Q.   And I'm going to try to move quickly. I think  
21   there was a misunderstanding about the -- the start time,  
22   but you're prepared to go forward; right?

23                   A.   Certainly.

24                   Q.   Okay. I'm going to give you what we're first

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1 Q. And you have not issued and do not hold  
2 opinions on any of the other products; correct?

3 A. That's correct.

4 Q. Okay. And you'll agree with me that a medical  
5 device manufacturer has a responsibility to design their  
6 product so as to minimize the potential for injury to  
7 patients; correct?

8 A. That's correct.

9 Q. And that -- you'll agree with me that, in  
10 order to do that, a device manufacturer must consider and  
11 understand the medical condition that the device is  
12 designed to treat; correct?

13 A. That's correct.

14 Q. And it must also consider and understand the  
15 anatomical location where that device is implanted;  
16 correct?

17 A. That's correct.

18 Q. Where is a TVT-R device implanted?

19 A. As I understand it -- and I may speak very  
20 generically -- that it is in the same location but  
21 different -- in a different way of implanting than the  
22 TVT-O.

23 Q. Okay.

24 A. One's inside-out and the other's outside-in.

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1 That's my basic understanding.

2 Q. Okay. But it's your understanding that the  
3 implant site for both the TVT-R and the TVT-O are the  
4 same?

5 A. That's my understanding.

6 Q. Okay. Did anyone at Ethicon ever tell you  
7 that?

8 A. I can't recall. I believe I read that.

9 Q. Okay. Did you look at the instructions for  
10 use on where the two products were implanted?

11 A. Yes. That was the best of my recall.

12 Q. Do you know what the obturator space is?

13 A. Vaguely, anatomically, yes.

14 Q. Okay. Sitting here today, do you understand  
15 that the TVT Retropubic and the TVT Obturator are  
16 implanted into different locations in a woman's pelvis?

17 A. It was my understanding that the mesh  
18 material, essentially, winds up, more or less, in the same  
19 location.

20 Q. Okay. And is that understanding that you have  
21 concerning the two devices, did that factor into the  
22 opinions that you gave in this case and the reports  
23 identified as 14 and 15?

24 A. I would have to say yes, it did.

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1           Q.    Okay.  And you agree with me that it's  
2   important, when you are designing a device or doing --  
3   scratch that.

4                    You'll agree with me that it's important, when  
5   you're doing a risk assessment of a device, to understand  
6   where the device is going to be placed in the body;  
7   correct?

8           A.    Yes.

9           Q.    And you'll agree with me that it's important  
10   to understand the surgical approach that's going to be  
11   used to implant those different devices; correct?

12          A.    Yes, and that's what I tried to understand.

13          Q.    Okay.  And you tried to understand that based  
14   on the documents that you looked at and identified in your  
15   reliance list?

16          A.    Yes.

17          Q.    Okay.  Did you understand when you put -- do  
18   you have any understanding of whether the trocars that are  
19   used to implant the TVT-R are the same or different than  
20   the trocars that are used to implant the TVT-O?

21          A.    It's my understanding that the TVT-O trocars  
22   are somewhat different.

23          Q.    Okay.  And they are a different shape;  
24   correct?

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1 A. Yes.

2 Q. And that's used because there's a different  
3 surgical placement of the TVT-O over the TVT-R; correct?

4 A. It was my understanding that it was because of  
5 the surgical approach.

6 Q. Okay. And when you say surgical approach, are  
7 you referring to what you call the inside-out versus the  
8 outside-in approach?

9 A. Yes.

10 Q. And so it's your understanding that the  
11 trocars -- well, first of all, which one of these is  
12 implanted with the inside-out approach; do you recall?

13 A. Yes.

14 Q. Okay.

15 A. The TVT-O.

16 Q. Okay. Inside-out, let me ask if we're on the  
17 same page. Inside-out is when you go in through the  
18 vagina and you put the trocars out of the pelvis by  
19 introducing it through the vagina first?

20 A. That's my understanding.

21 Q. Okay. And the outside-in approach that you  
22 believe is used with the TVT-R is when you go from the  
23 outer area in the abdomen or the pelvis and you push the  
24 trocars through into the vagina and then pull them up

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1 again; correct?

2 A. That's right.

3 Q. And it's your understanding that those  
4 different approaches, the inside-out versus the  
5 outside-in, are what account for the different shapes of  
6 the trocars that are used with the TVT-R and the TVT-O  
7 procedure?

8 A. That's my perception from reading the  
9 documents I read.

10 Q. Okay. And you took that -- those -- the  
11 difference in the trocars on the outside-in and the  
12 inside-out approach into account when you were preparing  
13 your reports on these two devices; correct?

14 A. Yes.

15 Q. Okay. I'm going to skip --

16 A. Not in a specific way of my judgment of their  
17 design, good or bad, but that they needed to be shaped  
18 differently because of the procedure.

19 Q. Okay. And since you're not opining on the  
20 TVT-S or the Exact or Abbrevio, we've short-circuited some  
21 of my exam today, so that's good.

22 And you'll agree with me that a medical device  
23 manufacturer, when making a permanent device for implant  
24 into the human body, has to be an expert on the material



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CERTIFICATE

I, Barbara J. Carey, a Registered Professional Reporter and Notary Public for Anoka County, Minnesota hereby certify that I reported the Deposition of Elaine Duncan, on the 31st day of March, 2016, in Minneapolis, Minnesota, and that the witness was by me first duly sworn to tell the whole truth;

That the testimony was transcribed under my direction and is a true record of the testimony of the witness;

That I am not a relative or employee or attorney or counsel of any of the parties or a relative or employee of such attorney or counsel;

That I am not financially interested in the action and have no contract with the parties, attorneys, or persons with an interest in the action that affects or has a substantial tendency to affect my impartiality;

That the right to read and sign the deposition by the witness was not waived;

IN WITNESS WHEREOF, I have hereunto set my hand this 4th day of April, 2016.

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Barbara J. Carey  
Registered Professional Reporter  
Notary Public